CRITICISMS OF EPIDEMIOLOGY

The EPA's risk assessment relies heavily on a cumulative risk estimate for ETS of 1.19, calculated by meta-analysis of eleven U.S. epidemiologic studies of spousal smoking. In epidemiology, a risk estimate of 1.0 indicates no increase or decrease in reported risk. Moreover, epidemiologists generally agree that any estimated risk of less than 2.0 should be deemed "weak."[1] Given this weak association, the studies underlying EPA's conclusion should be critically examined, as, for example, EPA did not address fundamental questions regarding the detection limits of an epidemiologic study, or whether confounding factors have been effectively ruled out.

- A point estimate for "spousal smoking" below 2.0, given the very nature of epidemiology, may be due to some factor or factors associated with marriage to a smoker (e.g., diet, lifestyle, occupation, socioeconomic status, etc.).[2-12]

- Epidemiologic studies have reported risk estimates for lung cancer in nonsmokers in excess of 2.0 for these factors. The scientific literature suggests that such estimates may be large enough to account completely for the reported association between spousal smoking status and lung cancer.

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- The EPA failed to investigate whether the statistically significant associations reported in six of the 30 epidemiologic studies[13-18] could be the result of confounding by potential risk factors. The EPA failed to consider the large body of literature independent of the spousal smoking studies that addresses such factors.[2-12,19-31]

- EPA took the position that it was necessary to identify a <u>single</u> confounder, applicable across all the studies. Given the disparate study populations, methods, and analyses employed in the 30 studies, this is an unwarranted and unscientific expectation.[12]

- Moreover, the scientific literature identifies several sources of possible bias in the spousal smoking studies.[32-42] These include publication bias, recall (exposure) bias, disease misclassification and smoking status misclassification.

- The Risk Assessment acknowledges only <u>one</u> possible bias, smoking status misclassification, and adjusts for it by employing an unpublished scientific model that had not been subjected to external peer review. The model uses a misclassification rate that is not representative of the U.S. population.[43-44]

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- The ETS Risk Assessment is not based on accurate or verifiable information concerning exposure to ETS: the spousal smoking studies on which its conclusions are based used questionnaires to collect data on recall of exposures. The accuracy of those data depends on an individual's ability to recall past events, such as how much a husband smoked in the past 20 to 30 years.[32,33,36]

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CONFIDENCE INTERVALS

The EPA lowered the confidence interval generally used in the individual spousal smoking studies from 95% to 90%. This was apparently an attempt to obtain statistical significance for the cumulative risk estimate calculated by meta-analysis of the U.S. studies.

- A confidence interval measures the probability that a statistical association was obtained by chance. Therefore, the net effect of lowering the confidence interval from 95% to 90% is to double the likelihood that chance is artificially ruled out as a possible explanation for the apparent association, i.e., that it is artificially concluded that the association is statistically significant.

- EPA's use of a lower confidence interval may be questioned on a scientific basis because:

  The EPA and other federal agencies have generally used 95% confidence intervals in other risk assessments that have relied upon epidemiologic studies.

  Virtually all of the ETS epidemiologic studies upon which the EPA relied originally reported 95% confidence intervals.

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The EPA's 1990 draft risk assessment on ETS used 95% confidence intervals.

Lowering the confidence interval was apparently the only way the EPA could reach its conclusion of a statistically significant increased risk for the combined U.S. studies.

The ETS Risk Assessment does not discuss the effect that lowering the confidence interval had on the data.

- The magnitude of the effect of this manipulation of the data is revealed when the standard 95% confidence interval is used. A meta-analysis of the U.S. studies employing the EPA's assumptions and using a 95% confidence interval reports no statistically significant summary risk estimate.[1]

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META-ANALYSIS

To reach the conclusion of the Risk Assessment, namely, a statistically significant risk estimate, the EPA used a statistical technique known as meta-analysis to combine data from eleven epidemiologic studies of spousal smoking conducted in the United States.[1-11]

- The EPA's meta-analysis did not aggregate similar data. This violates a fundamental principle of meta-analysis. For example, all of the studies employed different questionnaires and different assessments of past exposure; five of the studies failed to match cases with controls; and the criteria for control selection were different in each study.[12]

- The EPA has not addressed the issue of the aggregation of dissimilar data in its meta-analysis. Moreover, although EPA identifies the exposure index of spousal smoking as a "common thread" through the studies that justifies the use of meta-analysis, even this parameter is defined differently among the studies.

- Not one of those eleven studies originally reported a statistically significant overall risk estimate for lung cancer. Thus, chance was not effectively ruled out as an explanation for the reported overall association between

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spousal smoking and lung cancer in nonsmokers in any of those studies, contary to EPA's meta-analysis.

- The EPA also reviewed 19 other epidemiologic studies from seven countries other than the United States.[13-31] Of these 19 studies, 13 reported no statistically significant overall risk estimate for spousal smoking and lung cancer.

- Put another way, of the 30 studies reviewed by the EPA, the overall risk estimates reported in 24 (a full 80%) of them did not support the conclusion of the Agency's meta-analysis.

- Even positive risk estimates (greater than 1.00) that do not achieve statistical significance are compatible with the null hypothesis of "no association" between spousal smoking and lung cancer. Reported overall risk estimates in six non-U.S. studies are statistically significant, but the EPA did not ascertain whether or not these purported associations are due to some feature that is coincidental to "marriage to a smoker" (e.g., common diet, occupational exposures, socio-economic status and other lifestyle characteristics).

- Nevertheless, EPA relied on the cumulative risk estimate derived from the meta-analysis of eleven U.S. epidemiologic studies of spousal smoking for its classification of ETS as a

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known human carcinogen.

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